IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO. 2187**
THIS DOCUMENT RELATES TO:	
CAROLYN JONES	**2:11-cv-00114**
v.	
C. R. BARD, INC.	

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST PLAINTIFF CAROLYN JONES

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INTRODUCTION

Carolyn Jones began experiencing urinary incontinence and frequency, difficulty with bowel movements and a heaviness and pressure in her vagina in 2008. Ms. Jones was required to use pads to catch her urine and to splint herself when having a bowel movement (the need to place your fingers within the vagina and apply pressure to assist in the release of stool). Additionally, she was able to feel a bulge in her vagina. Ms. Jones' activities were hindered by her symptoms, and she was experiencing constant discomfort. Ms. Jones' medical history also includes advanced diabetes with retinopathy.

Initially, Ms. Jones sought treatment from her primary care physician and his physician's assistant, and then sought treatment with Dr. David Williams, an experienced gynecologist. Dr. Williams evaluated Ms. Jones and recommended implanting the Avaulta Plus™ Biosynthetic Support System ("Avaulta Systems" or "Avaulta Plus™") for pelvic organ prolapse and the Align® TO Urethral Support System (Align®) sling to treat Ms. Jones's urinary incontinence. This was accomplished in a surgical procedure on August 26, 2008. Ms. Jones alleges that the Avaulta Plus™ and/or Align® have caused her to experience recurring urinary tract infections, urinary incontinence, and pain. Ms. Jones has had two surgical revision procedures and has recently begun treatment with a new colorectal physician whose records have not been reviewed.

Over the course of discovery, it has become increasingly clear that Bard is not to blame for Ms. Jones's alleged damages. It is also clear that many of Plaintiff's legal theories are without evidentiary support and therefore subject to dismissal as a matter of law. Although Ms. Jones's design defect claim will not be ripe for summary adjudication until the completion of

expert discovery[1], her other causes of action are presently subject to dismissal for the following reasons:

- There is no evidence that Ms. Jones' Avaulta Plus™ contained a manufacturing defect. To the contrary, the undisputed evidence demonstrates that the products implanted in Ms. Jones were manufactured in accordance with, and therefore did not differ from, the intended specifications.

- Plaintiff's failure to warn claim is barred by the learned intermediary doctrine because the undisputed evidence establishes that Bard's warnings related to the complications of erosion and infection were specifically warned of in the IFU and Plaintiff cannot establish causation by showing that any revised or additional warning would have prevented Dr. Williams from implanting Bard's products into Plaintiff.

- Plaintiff's claims for breach of express warranty fail because there is no evidence that Bard made any express representations to Plaintiff about the Avaulta Plus™ or that Plaintiff relied on any information from Bard.

- Plaintiff's claims for breach of implied warranties (merchantability and fitness for a particular purpose) fail because Bard's devices were cleared by the FDA and were accompanied by Instructions for Use ("IFU") that warned of the products' risks. Additionally, Plaintiff did not rely on Bard when the products were implanted in her.

- As a matter of law, Plaintiff's claims under Mississippi's Consumer Protection Laws must be dismissed because Plaintiff did not try to resolve her claim through an informal dispute settlement program before filing her Complaint.

- Assuming Plaintiff's claim for negligent inspection, packaging, marketing, and selling were intended to reach beyond Plaintiff's manufacturing, design, and warnings claims, there is no evidence to support such claims. Plaintiff has not established Bard breached the applicable standard of care, and they have not established any such alleged breach proximately caused her damages.

Therefore, and for the reasons explained more fully below, Bard respectfully requests that the Court grant its Motion for Partial Summary Judgment and dismiss Plaintiff's claims for manufacturing defect (negligent and strict liability), failure to warn (negligent and strict liability), breach of warranty (express and implied), violations of Mississippi's Consumer Protection Statutes, and negligent inspection, packaging, marketing, and selling.

[1] In accordance with PTO 72, the deadline for filing "Daubert-based" dispositive motions is June 1, 2013. Consistent therewith, Bard respectfully reserves the right to move for summary judgment as to additional causes of action (including, without limitation, design defect) and/or on additional grounds (lack of specific causation).

STATEMENT OF MATERIAL FACTS

I. The FDA Cleared Bard's Avaulta Systems for Marketing in the United States, and the FDA Never Took Enforcement Action Against Bard.

Congress has granted the FDA the authority to regulate medical devices, which are heavily scrutinized by the FDA both before and after they are placed on the market. The Avaulta Systems are Class II devices, which, pursuant to FDA regulations, must be cleared by the FDA pursuant to the 510(k) process before they can be legally marketed. *See* 21 C.F.R. § 878.3300 (classifying surgical mesh as a Class II device). As required by the 510(k) process, Bard submitted to the FDA the design, intended use, labeling, and performance data for the Avaulta Systems before marketing Bard marketed them. (*See* AVA20020326-446.)[2]

It is undisputed that the FDA cleared Bard's Avaulta Systems to be marketed in the United States. Additionally, even after the Avaulta Systems were being marketed, Bard subsequently submitted to the FDA two separate 510(k) submissions concerning minor modifications to the Avaulta Systems. The FDA cleared both submissions without requesting any additional information or actions. (*See* AVA2E3574268-70; AVA20020763-64.) In the course of Bard's submissions to the FDA, the FDA never informed Bard that the labeling or design for the Avaulta Systems was not satisfactory. Furthermore, the FDA never took any enforcement actions against Bard in relation to the Avaulta Systems.

II. Ms. Jones Experienced Urinary Stress Incontinence and Pelvic Organ Prolapse.

In 2008, Ms. Jones, began experiencing urinary stress incontinence and was diagnosed with pelvic organ prolapse. At that time, Ms. Jones had been separated from her husband for some years and was receiving Social Security Disability due to diabetes and COPD. (*See* August

[2] The relevant portion of Bard's 510(k) submission for its Avaulta Systems is annexed as Exhibit "H" to the Motion for Partial Summary Judgment on Plaintiffs' Punitive Damage Claim, Or in the Alternative to Bifurcate the Trial with a Separate Punitive Damages Phase.

6, 2012 Deposition of Carolyn Jones ("Jones Dep., v.1") at 38:10-39:22, 62:16-63:9[3].) Although medical records indicate that Ms. Jones was diagnosed with a cystocele in 2006, Ms. Jones testified that she did not begin experiencing the feelings of urinary incontinence and pelvic organ prolapse until approximately 6 months prior to her October, 2008 surgeries. (Jones Dep., v.1 at 103:1-10.)

At that time in early 2008, Ms. Jones started feeling as if her "bladder had dropped," was "wetting all over herself," and would have to use her hand to splint her rectum when she had a bowel movement. (*Id.* at 93:9-94:16.) Ms. Jones had urinary urgency and leaking with sneezing and laughter (*Id.* at 112:25-113:10.), lost control of her urine (*Id.* at 111:4-9.), and had increased urinary frequency (*Id.* at 116:10-23.). Additionally, every time Ms. Jones would urinate she would feel as if she could not void completely and that she would have to wait after urinating "until it started up again" or she would be forced to run right back to the toilet. (*Id.* at 107:7-108:17.) Ms. Jones' described her incontinence experience by testifying, "you couldn't go nowhere or do anything. Like you feel like you was going to go somewhere and urinate on yourself…." (*Id.* at 100:2-12.) She was wearing a sanitary pad every day (*Id.* at 113:20-114:6.) and was advised by her family physician to practice slowing her urine as an exercise to treat her incontinence. (*Id.* at 114:19-115:21.)

Ms. Jones also experienced the feeling of pelvic organ prolapse for approximately 6 months prior to her 2008 surgery. As she explained - she felt a "heaviness" or her pressure in her lower abdomen and she could feel that the bladder had dropped. (*Id.* at 93:8-20, 102:2-4.) She had to splint her recutum with her hand when she was having a bowel movement (*Id.* at 93:25-94:16.), occasionally had to strain or struggle to have a bowel movement (*Id.* at 1093-6.), and

[3] A true and correct copy of the transcript of Carolyn Jones's August 6, 2012 deposition is annexed to the accompanying Motion as Exhibit "A."

occasionally had bleeding (*Id.* at 111:12-25.). This bothered Ms. Jones because, as she described, "it did bother me because, I mean, thinking something is going to fall out of you any time….I'm scared to do any activity." (*Id.* at 104:15-18.)

During this time, Ms. Jones was treated by her family physician's office, specifically the nurse practitioner. But as the problems worsened, the nurse practitioner advised Ms. Jones to seek treatment with a gynecologist, David Williams, M.D. (*Id.* at 122:10-123:7.)

III. Dr. Williams Made the Independent Medical Decision to Treat Ms. Jones' Pelvic Organ Prolapse And Urinary Stress Incontinence.

Dr. Williams is a Board Certified Obstetrician/Gynecologist in private practice in New Albany, Mississippi, since 1987. (*See* October 9, 2012 Deposition of Dr. David Williams ("Williams Dep.") at 6:4-7:2[4].) Dr. Williams has been treating pelvic organ prolapse and stress urinary incontinence since that time. (*Id.* at 7:16-8:2.) In 2006, Dr. Williams attended a Bard MDU Physician Education- Avaulta Training in Chicago and began implanting Avaulta mesh in his private practice that same year. (*Id.* at 11:2-13:11.). In that training, he was given a didactic lecture, an anatomical discussion and then participated in a cadaver lab. (*Id.* at 13:12-19.)

Dr. Williams diagnosed Ms. Jones with a cystocele (grade 2), a rectocele (grade 3) and stress urinary incontinence. (*Id.* at 49:14-50:25.) He determined that Ms. Jones needed surgical repair using Avaulta Plus™ and an Align® sling. (*Id.*)

IV. Bard Warned About the Risks Associated With the Avaulta Plus™ And the Complications Ms. Jones Ultimately Experienced.

The Avaulta Plus™ implanted in Ms. Jones was accompanied by an IFU and Dr. Williams agrees that generally medical devices include these instructions. (*Id.* at 33:23-34:7.) However, Dr. Williams testified that did not read the IFU for the Avaulta Plus™ that was

[4] A true and correct copy of the transcript of Dr. Williams' October 9, 2012 deposition is annexed to the accompanying Motion as Exhibit "B."

implanted in Ms. Jones. (*Id.* at 34:8-12, 94:13-21.) Had he read the IFU, Dr. Williams would have seen the following Adverse Reactions:

> Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, *mucosal or visceral erosion, infection*, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum or any viscera may occur during needle passage.[5]

(Avaulta IFU at p. 4.)

Dr. Williams performed surgery on Ms. Jones on August 26, 2008. (Williams Dep. at 59:17-60:8.) Dr. Williams implanted the Avaulta Plus™ system an Align® sling. (*Id.* at 59:17-60:8, 65:3-5) Following her surgery, Ms. Jones reported complications with erosion and infection, both conditions within the IFU Adverse Reactions section. (*See* September 5, 2012 Deposition of Carolyn Jones ("Jones Dep., v.2") at 195:23-196:7[6]; Williams Dep. at 76:21-79:19.)

APPLICABLE LAW

I. This Court Should Apply Mississippi's Choice-of-Law Rules.

When an action is transferred from one federal court to another—whether for convenience pursuant to 28 U.S.C. § 1404(a) or by the Judicial Panel on Multidistrict Litigation pursuant to 28 U.S.C. § 1407—the transferee court must apply the law of the state in which the action was originally filed. *See, e.g.*, *Chang v. Baxter Healthcare Corp.*, 599 F.3d 728, 732 (7th Cir. 2010) ("When a diversity case is transferred by the multidistrict litigation panel, the law applied is that of the jurisdiction from which the case was transferred...."). Plaintiff Carolyn Jones commenced this action in the United States District Court for the Northern District of

[5] A true and correct copy of the Avaulta Plus™ Instructions for Use is annexed to the accompanying Motion as Exhibit "C."

[6] A true and correct copy of the transcript of Carolyn Jones's September 5, 2012 deposition is annexed to the accompanying Motion as Exhibit "D."

Mississippi. This Court should therefore apply Mississippi's choice-of-law rules to determine which substantive laws shall govern this case. *See In re Air Disaster at Ramstein Air Base, Ger*., 81 F.3d 570, 576 (5th Cir.1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied"); *see also In re Digitek Prod. Liab. Litig*., MDL No. 2:08-md-01968 (JRG), 2010 WL 2102330, at *7 (S.D. W.Va. May 25, 2010) (applying choice-of-law rules from transferor court to consolidated products liability class actions).

II. Under Mississippi's Choice-of-Law Rules, the Substantive Laws of Mississippi Govern this Case.

Mississippi applies the "center of gravity" or "most significant relationship" test as it is defined in the Restatement (Second) of Conflicts of Laws § 145 to determine which state's substantive law applies to tort actions. *See Mitchell v. Kraft*, 211 So.2d 509, 516 (Miss. 1968) (enunciating "center of gravity" test in wrongful death case). Section 145 provides the following:

> (1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.
>
> (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:
>
> > (a) the place where the injury occurred,
> > (b) the place where the conduct causing the injury occurred,
> > (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and
> > (d) the place where the relationship, if any, between the parties is centered.
>
> These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second) of Conflicts of Laws § 145; *see Mitchell*, 211 So.2d at 515.

When applying these factors, it is apparent that Mississippi has the most significant relationship with this legal action. At all times relevant to this case, Plaintiff Carolyn Jones is and was a resident of the State of Mississippi. (Compl., ¶ 1[7].) Additionally, it is undisputed that the surgery to implant Mrs. Jones's Avaulta Plus™ and Align® products was performed in Mississippi and that her subsequent related procedures and alleged injuries occurred in Mississippi. Indeed, the relationship between the Parties is and was centered in the State of Mississippi, the only state where Plaintiff has come into contact with Bard's products. For these reasons, the substantive law of Mississippi governs Plaintiff's claims in this action. *See, e.g., Price v. Litton Systems, Inc.*, 784 F.2d 600, 604-05 (5th Cir. 1986) (applying Mississippi choice of law and holding that Alabama substantive law applies because it was the place of injury, the center of the parties' relationship, and the residence of the decedents at the time of the accident).

SUMMARY JUDGMENT STANDARD

To obtain summary judgment, Bard must demonstrate an absence of disputed issues of material facts such that Bard is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). Summary judgment is warranted if Plaintiff cannot make a showing sufficient to establish each element for which Plaintiff bears the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Although the Court will view facts and inferences in the light most favorable to Plaintiff, *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986), Plaintiff must nonetheless offer some "concrete evidence from which a reasonable juror could return a verdict in [her] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Concrete evidence requires more than a mere "scintilla" of evidence, *id.* at 252, and Plaintiff cannot avoid summary judgment simply by introducing conclusory allegations or unsupported

[7] A true and correct copy of Plaintiff's Complaint is annexed to the accompanying Motion as Exhibit "E."

speculation. *See, e.g., In re Digitek Prods. Liab. Litig.*, 821 F. Sup. 2d 822, 837 (S.D. W.Va. 2011) (granting summary judgment because "there is completely lacking a cogent argument or genuine issue of material fact on the questions of defect and its cause of resulting harm").

ARGUMENT

I. Summary Judgment is Warranted for Plaintiff's Claims Covered Under The Mississippi Products Liability Act of 1993.

In 1993, the legislature enacted the Mississippi Products Liability Act ("MPLA"), Miss. Code § 11-1-63[8], which is applicable to "any action for damages caused by a product except for damage to the product itself" filed after July 1, 1994. The terms of the MPLA codify four causes of action which can be asserted in a products liability lawsuit. *See* Miss. Code §11-1-63. Under the Act, a manufacturer of a product will only be liable if a plaintiff proves, by a preponderance of the evidence, that at the time the product left the control of the manufacturer: (1) the product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications; (2) the product was defective because it failed to contain adequate warnings or instructions; (3) the product was designed in a defective manner; or (4) the product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product[9]. *Id.* In addition, for each of these aforementioned claims, a plaintiff must prove that the defective condition rendered the product unreasonably dangerous to the consumer and that such condition of the product proximately caused their damages. *Id.* Whether asserted under strict liability or negligence, Plaintiff's claims for manufacturing defect and failure to warn (warnings defect) are governed by the requirements of the MPLA, in addition

[8] A true and correct copy of Mississippi Code Annotated §11-1-63 is annexed to the accompanying Motion as Exhibit "F."

[9] In sum, the MPLA expressly recognizes and codifies the three traditional categories of product defects - design defects, manufacturing defects, and warning defects – in addition to breach of express warranty.

to her claims for breach of express warranty. *See Dykes v. Husqvarna Outdoor Products, N.A., Inc.*, 869 F. Supp. 2d 749, 755 (S.D. Miss. 2012).

A. Plaintiff's Manufacturing Defect Claims Fail for Lack of Evidence.

To prove a claim of manufacturing defect under the MPLA, a plaintiff must establish that "the product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications." Miss. Code §11-1-63; *see also Dykes*, 869 F. Supp. 2d at 755 (S.D. Miss. 2012). The same standards apply whether the claim is asserted under the MPLA or as a common-law negligence claim. *Dykes*, 869 F. Supp. 2d at 760 ("While a plaintiff may bring a common-law negligence claim in addition to a products liability claim under the Mississippi Products Liability Act, the requirements of the MPLA are still applicable.") (citation omitted).

Here, Plaintiff has adduced no evidence that the Avaulta Plus™ product implanted in her had a manufacturing flaw or defect. In other words, Plaintiff can refer to no admissible evidence, whether documentary or testimonial, from which it could be inferred that Ms. Jones' specific device in any way deviated from the underlying specification for all Avaulta Plus™. Indeed, none of Plaintiff's experts address this issue. For this reason alone, Plaintiff's claims for alleged manufacturing defect fail as a matter of law such that Bard is entitled to summary judgment. *See, e.g., Dykes*, 869 F. Supp. 2d at 760 (granting summary judgment on plaintiff's manufacturing defect claim because plaintiff offered no evidence that the product deviated in any way from other units); *Shelter Ins. Co. v. Mercedes-Benz USA, LLC*, 236 F. App'x 45, 47 (5th Cir. 2007) (affirming trial court's directed ruling on plaintiff's manufacturing defect claim for the same reason).

Even though Plaintiff bears the burden of proving a manufacturing defect, Bard has presented substantial evidence that Ms. Jones's Avaulta Plus™ product was in fact manufactured in accordance with Bard's specifications. The Avaulta and other Bard products are subject to a carefully controlled manufacturing process, and are exposed to quality assurance tests and inspections through the production process. (Bigby Decl. ¶ 4.)[10] Each of the steps taken during the manufacturing process is described in the lot history documentation, which describes the visual and dimensional tests and inspections for each Lot of manufactured devices. (*Id.*) The lot history documentation for the lot that included the Avaulta Plus™ implanted in Ms. Jones reflect that all devices in those lots were manufactured in accordance with Bard's specifications, passed all quality control inspections, and were free from any manufacturing defect at the time they were released for sale, and were packaged with the warnings and labeling cleared by the FDA. (*Id.* ¶ 6.)

On this record, Bard is entitled to summary judgment on Plaintiff's manufacturing defect claims (both strict liability and negligence).

B. Plaintiff's Warnings Claims Fail Under The Learned Intermediary Doctrine.

To prove a claim of failure to warn under the MPLA, a plaintiff must establish that "the product was defective because it failed to contain adequate warnings or instructions." Miss. Code §11-1-63. Plaintiff asserts a failure to warn claim under both strict liability and negligence theories and under Mississippi law, including the MPLA[11], summary judgment is warranted under both theories pursuant to the learned intermediary doctrine, which provides that:

[10] A true and correct copy of the Declaration of Laura Bigby is annexed to the Motion as Exhibit "G."

[11] Mississippi has codified the learned intermediary doctrine in the MPLA and provides that "[a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the

> The general rule is that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen. If the language of the warning is adequate then the drug manufacturer ordinarily is freed from liability.

Wyeth Laboratories, Inc. v. Fortenberry, 530 So. 2d 688, 691 (Miss. 1988) (citations and quotations omitted); *see also Coleman v. Danek Med. Inc.*, 43 F. Supp. 2d 637, 646 (S.D. Miss. 1999) (applying Mississippi law and granting summary judgment for defendants on plaintiff's failure to warn claims for a medical device based on the learned intermediary doctrine). The rationale for the learned intermediary doctrine is "that the physician, through education, experience, and special training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular [prescription device] for a specific patient." *Windham v. Wyeth Laboratories, Inc.*, 786 F. Supp. 607, 611 (S.D. Miss. 1992) (citation omitted).

The adequacy of the warnings provided to a physician cannot be challenged if those warnings identify the specific risks that allegedly resulted in the plaintiff's injuries. *See, e.g.*, *Coleman*, 43 F. Supp. 2d at 647-48. Moreover, "[a] warning may be held adequate as a matter of law where the adverse effect that was ultimately visited upon the patient was one that the manufacturer specifically warned against." *Cather v. Cather Technology Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991) (citing *Fortenberry* 530 So.2d at 692-93); *see also Austin v. Will-Burt Co.*, 361 F.3d 862, 868-69 (5th Cir. 2004) (applying Mississippi law); *Swayze v. McNeil Labs., Inc.*, 807 F. 2d 464, 469 (5th Cir. 1987) (applying Mississippi law) (drug warnings were adequate where they were contained in package insert).

Even if a manufacturer's warnings were inadequate, a plaintiff cannot survive summary judgment unless they can establish an issue of fact pertaining to causation. Specifically, Mississippi law requires a plaintiff to establish that an adequate warning would have

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characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product." Miss. Code §11-1-63 (c)(ii).

prevented the plaintiff's injury by showing both "(1) that an adequate warning would have prevented the treating physician from administering the drug; and (2) that the injury would not have occurred had the drug not been administered." *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992) (applying Mississippi law).

As demonstrated more fully below, the Court should grant summary judgment on Plaintiff's failure to warn claims because Bard's warnings were adequate as a matter of law and because Plaintiff cannot establish causation by showing that any warning would have prevented Plaintiff's implanting physician from using the Avaulta Plus™ product implanted in her.

1. Bard's Warnings as They Relate to Plaintiff's Claimed Complications of Erosion and Infection are Adequate as a Matter of Law.

The learned intermediary bars Plaintiff's failure to warn claims as they relate to erosion of the Avaulta Plus™ device and infection because, as a matter of law, Bard adequately warned of those specific risks and complications associated with the Avaulta Plus™ product about which Ms. Jones now complains. (*See* Jones Dep., v.2 at 195:23-196:7.) The Southern District of Mississippi's decision in *Cather* is directly on point. *See Cather*, 753 F.Supp 634. In *Cather*, the plaintiff claimed the defendant manufacturer failed to adequately warn him of the risks of venous thrombus and embolism, complications he experienced from the placement of a catheter. *Id.* at 639-41. The court granted summary judgment on plaintiff's failure to warn claims as it related to these two alleged complications and held that defendant's warning was adequate as a matter of law because venous thrombosis and embolism were specifically mentioned in the manufacturer's physician's instructions. *Id.* at 640. In holding that defendant's warning as it related to these two complications[12] were adequate as a matter of law, the court did not inquire

[12] The court granted summary judgment in favor of defendants on plaintiff's failure to warn claim as it related to other alleged complications not mentioned in the physician's instructions (pneumonia and blood clotting) on the basis that plaintiff failed to show any evidence of causation. *See Cather*, 753 F.Supp at 640-41.

whether the physician who placed the catheter had read or was aware of the physician's instructions. *Id.* at 639-41 (emphasis added).

Here, Plaintiff alleges Bard should have provided a laundry list of different or additional warnings. (*See* Master Compl. ¶ 45, 66, 77.) Plaintiff cannot dispute, however, that the IFU that accompanied Ms. Jones's Avaulta Plus™ warned about the risk of erosion and infection - complications of which she now complains. Indeed, the **ADVERSE REACTIONS** section of the IFU packaged with Ms. Jones's Avualta Plus stated:

> Potential adverse reactions are those typically associated with surgically implantable materials, including hematoma, seroma, *mucosal or visceral erosion*, *infection*, inflammation, sensitization, dyspareunia, scarification and contraction, fistula formation, extrusion and recurrence of vaginal wall prolapse. Perforations or lacerations of vessels, nerves, bladder, bowel, rectum or any viscera may occur during needle passage.

(Avaulta Plus™ IFU at p. 4.)

Accordingly, Bard's warnings accompanying the Avaulta Plus™ device related to erosion and infection, Ms. Jones' chief complaints, are adequate as a matter of law and the Court should dismiss Plaintiff's claims for failure to warn as they relate to those complications.

2. Plaintiff Cannot Establish Causation Because Dr. Williams did Not Review Bard's IFUs Prior to Implanting the Avaulta Plus™ Product.

Even if Plaintiff could offer some evidence that Bard's warnings were not adequate as they related to erosion and infection associated with the Bard product implanted in Ms. Jones, Plaintiff's failure to warn claims fail in their entirety because there is no evidence that a different warning or additional warnings would have changed Dr. Williams' prescribing decision and therefore Plaintiff cannot establish the essential element of causation. Applying Mississippi law, the Fifth Circuit in *Thomas*, 949 F.2d at 814, held that to establish causation in a failure to warn claim a plaintiff must establish that "an adequate warning would have prevented the treating physician from administering the [device]." *See also Thomas v. Hoffman-La Roche, Inc.*, 731 F.

Supp. 224, 229 (N.D. Miss. 1989) ("A plaintiff in a [ ] products liability case has the burden of proving that an adequate warning to the prescribing physician would have altered the physician's conduct.") (emphasis added); *Arinder v. Danek Med., Inc.*, 1:95-CV-326-B-D, 1999 WL 1129647 (N.D. Miss. June 21, 1999) (citing the Fifth Circuit's decision in *Thomas* and granting defendants' motion for summary judgment because plaintiffs failed to establish that a different warning would have prevented the treating physician from administering the drug in question).

In this case, Plaintiff's implanting physician testified that he had not read the IFU for the Bard products he implanted in Ms. Jones. (*See* Williams Dep. at 34:8-12, 94:13-21.) Therefore, Plaintiff cannot establish the essential element of causation because an additional or different warning could not have prevented Dr. Williams from implanting the Avaulta Plus™ product into Ms. Jones, as Dr. Williams made clear in his testimony that he did not read the product IFUs in the first place. *See, e.g., Motus v. Pfiser, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001), *aff'd* 358 F.3d 659 (9th Cir. 2004) (granting summary judgment for defendant drug manufacturer on failure to warn claims for lack of causation because there was no evidence that the prescribing physician read or relied on the package insert before prescribing the drug in question); *Latiolais v. Merck & Co.*, No. CV 06-02208 MRP (JTLx), 2007 WL 5861354, at **3-4 (C.D. Cal. Feb. 6, 2007), *aff'd* 302 Fed. Appx. 756 (9th Cir. 2008) (granting summary judgment for defendant on failure to warn claim where prescribing physician did not read the product labeling because plaintiff could not prove that any inadequacy in the labeling caused her harm). Accordingly, the Court should dismiss Plaintiff's failure to warn claims.

C. Plaintiff's Claims for Breach of Express Warranty Fail for Lack of Evidence.

To prove a claim for breach of express warranty under the MPLA, a plaintiff must establish that "the product breached an express warranty or failed to conform to other express factual

representations upon which the claimant justifiably relied in electing to use the product." Miss. Code §11-1-63(a)(i)(4) . Plaintiff has not presented any evidence that Bard made an express representation to her about the Avaulta Plus™ product, or that she relied on any information from Bard in electing to use the product. Accordingly, Bard is entitled to summary judgment on Plaintiff's claims for breach of express warranty.[13] *See, e.g. McSwain v. Sunrise Med.*, Inc., 689 F. Supp. 2d 835, 848 (S.D. Miss. 2010).

II. Summary Judgment is Warranted for Plaintiff's Claims of Breach of Implied Warranties

Plaintiff's claims for breach of the implied warranty of merchantability (Miss. Code § 75-2-314) and the implied warranty of fitness for a particular purpose (Miss. Code § 75-2-315) also fail. Section 75-2-314 of the Mississippi code codifies the implied warranty of merchantability and states that:

> Goods to be merchantable must be at least such as:
> (a) Pass without objection in the trade under the contract description; and
> (b) In the case of fungible goods, are of fair average quality within the description; and
> (c) Are fit for the ordinary purposes for which such goods are used; and
> (d) Run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> (e) Are adequately contained, packaged and labeled as the agreement may require; and
> (f) Conform to the promises or affirmations of fact made on the container or label if any.

Miss. Code § 75-2-314.

The Bard product at issue was cleared for use by the FDA. As discussed above, the product was accompanied by an IFU that clearly labeled the product's uses and potential risks, and Ms. Jones' alleged complications from use of the Bard product were risks specifically

[13] For the same reasons as a claim brought under the MPLA, Plaintiff cannot prove a claim of breach of express warranty under Miss. Code 75-2-313 because there is no evidence that Bard made any "affirmation of fact or promise" to Plaintiff relating to the Avaulta Plus™ product implanted in her. *See* Miss. Code 75-2-313(1)(a).

warned about in the IFU. As such, Plaintiff's claims of breach of the implied warranty of merchantability fail.

Section 75-2-315 of the Mississippi Code codifies the implied warranty of fitness for a particular purpose and states that "where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is an implied warranty that the goods shall be fit for such purpose." Miss. Code § 75-2-315. Here, the evidence is clear that Ms. Jones relied solely on the skill and judgment of Dr. Williams and not on the seller, Bard, with the result that there is no implied warranty running in favor of Ms. Jones. Additionally, "Mississippi does not recognize an implied warranty of fitness for a particular purpose when the good is purchased for the ordinary purpose of a good of that kind." *Farris v. Coleman Co., Inc.*, 121 F. Supp. 2d 1014, 1018 (N.D. Miss. 2000). Here, Baptist Memorial Hospital, the medical facility where Plaintiff had her Avaulta Plus™ implanted, purchased that device for the ordinary purpose of a good of that kind – for the treatment of pelvic organ prolapse. Therefore, Plaintiff's claim for implied warranty of fitness for a particular purpose must fail and Bard is entitled to summary judgment.

III. Summary Judgment is Warranted for Plaintiff's Claims Under Mississippi's Consumer Protection Laws

Plaintiff makes claims against Bard for violating Mississippi's statutory consumer protection laws codified in Mississippi Code § 75-21-1, *et seq.* (*See* Compl. §§ 44-51.) Section 75-21-15 of these consumer protection laws requires that "[i]n any private action brought under this chapter, the plaintiff must have first made a reasonable attempt to resolve any claim through an informal dispute settlement program approved by the Attorney General." According to a long line of Mississippi federal and state court cases, a plaintiff's claims under this statutory scheme

must be dismissed as a matter of law if he or she did not try to resolve them through an informal dispute settlement program approved by Mississippi's Attorney General before filing a complaint. *See, e.g., Cole v. Chevron USA, Inc.*, 554 F.Supp.2d 655, 667 (S.D. Miss. 2007) ("[T]he court finds that the plaintiffs have failed to make a reasonable attempt to resolve their Mississippi CPA claims through an informal dispute settlement program as required under Section 75-24-15(2) and this failure is fatal to Count I of the Complaint."); *Taylor v. Southern Farm Bureau Cas. Co.*, 954 So. 2d 1045, 1049 (Miss. App. 2007) (affirming dismissal of plaintiff's MCPA claim against insurance company on various grounds including the plaintiff's failure to invoke and exhaust the administrative remedies provided for in §75-24-15(2). Since Plaintiff did not comply with this statutory requirement of attempting to resolve her claim through an approved informal dispute settlement program before filing her Complaint, Bard is entitled to summary judgment on these claims.

IV. Plaintiff's Claims Concerning Negligent Inspection, Marketing, Packaging, and Selling Fail For Lack of Evidence

In the Master Complaint, Plaintiffs contend Bard breached an alleged duty to Plaintiff by "[f]ailing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm . . ." (MC ¶ 64(d).) Plaintiffs further contend Bard breached alleged duties related to marketing, packaging, and/or selling its Avaulta Plus™ product. (MC ¶ 64(e).) To the extent Plaintiffs intends for these claims to go beyond their manufacturing, design, and warnings claims, the claims fail for lack of evidence.

To establish the elements of their negligence claim, Plaintiff must prove, among other things, both that Bard breached the alleged duty and that such breach caused Plaintiff's alleged harm. *See, e.g.*, *Entrican v. Ming*, 962 So. 2d 28, 32 (Miss. 2007) (For a claim of negligence, "[t]o prove the element of causation, both cause in fact and proximate cause must be shown.").

The testimony of an expert witness is required to establish both negligence (i.e., breach) and medical causation. *See, e.g. Edwards v. Campbell Clinic, Inc.*, 90 F. Supp. 2d 723, 725-26 (N.D. Miss. 2000) (applying Mississippi law and granting summary judgment because plaintiff did not "address any of the issues alleged in this matter requiring such expert testimony and/or proof, including, but not limited to . . . the defendants' failure to follow a proper standard of care . . . or causation.").

Here, Plaintiff has adduced no evidence in support of her claims for negligent inspection, marketing, packaging, and selling. None of Plaintiff's experts have testified that Bard breached the applicable standard of care in the manner it inspected, marketed, packaged or sold Ms. Jones specific Avaulta Plus™ product. Even if such testimony were deemed to exist, there is no evidence, and none of Plaintiff's expert witnesses have testified, that any such breach caused the alleged damages that are the subject of Plaintiff's claims. Due to the absence of any evidence of negligence or causation, the Court should grant summary judgment in Bard's favor on Plaintiff's claims for negligent inspection, marketing, packaging, and selling.

CONCLUSION

For the foregoing reasons, Defendant C.R. Bard, Inc. respectfully requests that the Court grant (1) summary judgment in its favor with respect to Plaintiff's claims for (A) manufacturing defect (negligent and strict liability), (B) failure to warn (negligent and strict liability), (C) breach of warranty (express and implied), (D) violations of Mississippi's Consumer Protection Statutes, and (E) negligent inspection, packaging, marketing, and selling and (2) grant Bard such other relief as the Court deems just and proper.

Dated: April 1, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2013, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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